

INTERNAL REVENUE SERVICE
P. O. BOX 2508
CINCINNATI, OH 45201

DEPARTMENT OF THE TREASURY

Date JUL 27 2001

Employer Identification Number:
[REDACTED]

DLN:
[REDACTED]

Contact Person:
[REDACTED]

ID# [REDACTED]
Contact Telephone Number:
[REDACTED]

Dear Applicant:

We have completed our consideration of your application for exemption from federal income tax under section 501(a) of the Internal Revenue Code as an organization described in section 501(c)(3).

You were formed as a nonprofit corporation in [REDACTED] on [REDACTED]. According to Article VIII of your Articles of Incorporation you were formed exclusively for scientific research purposes within the provisions of section 501(c)(3) of the Internal Revenue Code. More specifically, your Articles indicate your purpose shall include facilitating organ and tissue procurement for scientific research, and providing tissue for cancer research and therapeutic application.

You were founded by two individuals, who are also employed by you as Medical Director and Tissue Director for annual salaries of \$[REDACTED] and \$[REDACTED] respectively. Apparently, based on their considerable experience in the field, and after contacts with research companies, particularly major biomedical research companies, they determined that there is a substantial demand for a steady and reliable source of bodily tissue, such as skin, for use in the research work of such companies. The tissue is obtained from patients in various participating hospitals. Those hospitals have agreed verbally to participate and assist in procuring such tissue. The hospitals provide the tissue to you at no charge. Contacts have also been made with nursing homes, hospice programs and funeral directors for the purpose of reaching cooperative agreements.

As you receive orders from the research companies, the procurement process begins. The tissue you procure and provide to researchers generally has to meet certain precise and exacting standards set by the researchers. The actual research projects are undertaken at the initiative of the research companies and according to the protocol which they establish. The procurement process may also require that certain testing and preparation of the tissue be conducted to meet the agreed upon parameters of the research companies. You provide the tissue according to an agreed upon price as orders are placed. You maintain a price list for the various types of tissue, and order forms are used in the processing. The fees you charge for each tissue specimen range from \$[REDACTED] up to \$[REDACTED].

According to the budgets provided with your application, all receipts are projected to come from fees. Receipts for [REDACTED] are projected to be \$[REDACTED]. The majority of your expenditures will be for officers' salaries and travel. Estimated expenses for the year ended [REDACTED], your first full year of operation, total \$[REDACTED]. That amount includes Officers' Salaries of \$[REDACTED] and Travel expenses of \$[REDACTED].

Section 501(c)(3) of the Code provides for the exemption from federal income tax of organizations which are organized and operated exclusively for charitable and scientific purposes.

Section 1.501(c)(3)-1(c)(1) of the Income Tax Regulations provides that an organization will be regarded as "operated exclusively" for one or more exempt purposes only if it engages primarily in activities which accomplish one or more of such exempt purposes.

Section 1.501(c)(3)-1(d)(1)(ii) of the Income Tax Regulations provides that an organization is not organized or operated exclusively for exempt purposes unless it serves a public rather than a private purpose. To meet this requirement, it is necessary for an organization to establish that it is not organized or operated for the benefit of private interests.

Section 1.501(c)(3)-1(d)(2) of the regulations states that the term "charitable" is used in section 501(c)(3) of the Code in its generally accepted legal sense.

Under the proper circumstances, the promotion of health is considered to be a charitable purpose. Revenue Ruling 75-197, 1975-1 C.B. 156, holds that a nonprofit organization that operates a free computerized donor authorization retrieval system to facilitate transplantation of body organs upon a donor's death qualifies for exemption under section 501(c)(3) of the Code. The organization makes the necessary legal documents available to prospective organ donors, assigns a number to the donors and the same number to the completed legal documents, and stores the documents. Upon the donor's death, the hospital contacts the organization which then transmits to the hospital the documents authorizing the organ donation. The organization derives its funds from contributions and no fees are charged for its services. By operating in this manner and facilitating the donation of organs which will be used to save lives, the organization is serving the health needs of the community and is promoting health within the meaning of the general law of charity.

Section 1.501(c)(3)-1(d)(5)(i) of the regulations in defining the term "scientific" provides that since an organization may meet the requirements of section 501(c)(3) only if it serves a public rather than a private interest, a "scientific" organization must be organized and operated in the public interest.

Section 1.501(c)(3)-1(d)(5)(ii) of the regulations further provides that scientific research does not include activities of a type ordinarily carried on as incident to commercial or

industrial operations, as, for example, the ordinary testing or inspecting of materials or products.

Revenue Ruling 68-373, 1968-2 C.B. 206, illustrates the above. In that ruling, it was held that an organization which primarily engaged in testing drugs for commercial pharmaceutical companies did not qualify for exemption under section 501(c)(3) of the Code. The testing was required to comply with FDA requirements that drugs be tested for safety and efficacy before they can be marketed. The pharmaceutical companies selected the drugs to be tested and the results were freely available for publication. All of the organization's income was derived from the pharmaceutical companies in payment for testing services. The ruling held that the clinical testing of drugs is an activity ordinarily carried on as incidental to a pharmaceutical company's operations. It further held that the clinical testing of drugs for safety and efficacy in order to meet FDA requirements for marketing principally serves the private interest of the manufacturers rather than the public interest. Accordingly, because the organization served a private commercial interest rather than a public interest, the organization failed to qualify for exemption under Internal Revenue Code section 501(c)(3).

We recognize that you are operating in a field which may often be thought of as scientific, and that the tissue, or products, as they are sometimes referred to in your materials, which you provide to research companies may have to meet certain precise and exacting standards. We also recognize that those products may be of high importance to the business processes of those companies. However, an organization will not be considered operated for scientific purposes merely because its customers themselves may be engaged in research. Further, we understand that your work requires certain testing and preparation to maintain agreed upon parameters, but rather than engaging in research yourself, you are in the nature of a supplier of a needed product to customers who are themselves engaged in research. Also, many, if not most, of the research companies you supply appear to be commercial companies who will use the tissue you supply in the ordinary course of their business.

The tissue you locate, access, screen, and transport to your customers may have to meet certain parameters which they set, but many suppliers of goods and services, especially in the medical or scientific fields, have to ensure that their products and services meet the specialized needs of their customers. Your products are provided according to an agreed upon price as orders are placed by the research companies.

Like the organization described in Revenue Ruling 68-373, we believe your operations primarily serve the private commercial interests of the companies which purchase your products. In addition, you are not directly engaged in scientific research yourself, but merely operating as a supplier of goods for those companies which are. Accordingly, we have determined that you are not operated exclusively for scientific purposes within the meaning of section 501(c)(3) of the Code.

Further, unlike the medical retrieval system for donated organs to be used for transplant, which is described in Revenue Ruling 75-197 above, we have further determined that your operations are not promoting health within the meaning of the general law of charity. Unlike the organization described in that ruling, you charge fees for your services and your services are actively marketed to research companies. Your two founders, who recognized and developed the market for your products, are your principal employees. Specialized as you may be, we are unable to distinguish your methods of operation from those of an ordinary trade or business formed to provide needed products or services for a fee. Accordingly, we have determined that you are not operated exclusively for charitable purposes within the meaning of section 501(c)(3) of the Internal Revenue Code.

Consideration was given to whether you qualify for exemption under other subsections of section 501(c) of the Code. However, we have concluded that you do not qualify under another subsection.

Because we have determined that you are not operated exclusively for charitable or scientific purposes, recognition of tax-exempt status is denied. You should file federal income tax returns. Contributions to you are not tax-deductible under section 170 of the Internal Revenue Code.

If you do not agree with these conclusions, you may, within 30 days from the date of this letter, file in duplicate a brief of the facts, law and argument that clearly sets forth your position. If you desire an oral discussion of the issue, please indicate this in your protest. The enclosed Publication 892 gives instructions for filing a protest.

If you do not protest this proposed determination in a timely manner, it will be considered by the Internal Revenue Service as a failure to exhaust available administrative remedies. Section 7428(b)(2) of the Internal Revenue Code provides in part that, "A declaratory judgment or decree under this section shall not be issued in any proceeding unless the Tax Court, the Court of Claims, or the district court of the United States for the District of Columbia determines that the organization involved has exhausted administrative remedies available to it within the Internal Revenue Service."

If this determination letter becomes a final determination, we will notify the appropriate State Officials, as required by Section 6104(c) of the Code, that based on the information we have, we are unable to recognize you as an organization of the type described in Code section 501(c)(3).

If you agree with these conclusions or do not wish to file a written protest, please sign and return the enclosed Form 6018 as soon as possible.

[REDACTED]

If you have any questions, you may contact the person whose name, address and telephone number appear on the top of this letter.

Sincerely,

Steven T. Miller

Steven T. Miller
Director, Exempt Organizations

Enclosures
Form 6018
Publication 892